Suggested Readings

1. Michna, E., R.N. Jamison, E.D. Pham, F.L. Ross, D. Janfaza, S.S. Nedeljkovic, S. Narang, D. Palombi, and A.D. Wasan. Urine toxicology screening among chronic pain patients on opioid therapy: frequency and predictability of abnormal findings. Clinical J. Pain, 2007, 23(2):173-179.

2. Katz, N.P., S. Sherburne, M. Beach, R.J. Rose, J. Vielguth, J. Bradley, and G.J. Fanciullo. Behavioral monitoring and urine toxicology testing in patients receiving long-term opioid therapy. Anesthesia and Analgesia, 2003, 97(4):1097-1102.

3. Katz, N., and G.J. Fanciullo. Role of urine toxicology testing in the management of chronic opioid therapy. Clinical J. Pain, 2002, 18(4 Suppl):S76-82.

4. Fishman, S.M., B. Wilsey, J. Yang, G.M. Reisfield, T.B. Bandman, and D. Borsook. Adherence monitoring and drug surveillance in chronic opioid therapy. J. Pain and Symptom Management, 2000, 20(4):293-307.

Chapter 5: Referral and Patient Management

"The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients."
–FSMB Model Policy

Patients in chronic pain can present an extremely complicated picture. As we've seen, the subjective nature of pain is difficult in and of itself, but the collateral impact of patients' pain may disrupt their work and personal lives. In addition, patients in pain may have comorbid physical or emotional conditions for which they may be taking multiple medications. This complexity can challenge even the most broadly trained physicians, and can lead them into diagnostic and treatment areas that lie outside their expertise and professional comfort.

The tradition of medical referral exists to address this reality. In caring for patients in pain, referral to specialists or sub-specialists is common—and, indeed, often

necessary—for the typical clinician. Very few of us can practice effectively without help on a regular basis from colleagues who offer more specialized skills, perspectives, and capabilities in certain areas than we possess. Recognizing our own clinical limitations is a vitally important facet of medical professionalism. Because chronic pain affects every sphere of a patient's life, physicians should expect that they will need to request help from colleagues with expertise in diverse disciplines, such as mental health, addiction, physical rehabilitation, or any other medical or surgical subspecialty.

Here are a few basic requirements for facilitating the referral process:

1. Don't delay.

Almost all medical conditions or problems are easier to tackle early in their development rather than later. This applies with particular gravity to the case of chronic pain treatment with controlled substances. Valuable time can be wasted if a physician stubbornly tries to solve all problems by him or her self.

2. Invest in the pre-referral process.

Try to obtain the basic information that a consultant will need to efficiently evaluate your patient. This may seem obvious, but sometimes obtaining the required medical records, prescription records, or lab results can be logistically complicated.

3. Be as specific as possible in your request.

The more vague the referral, the less useful the consultation. Tell your consultant exactly how he or she can help you and your patient, and then be transparent in your documentation about the reason for consultation

and how it may affect treatment decisions and patient management. In particular, always state directly what you hope to achieve by your referral.

4. Know your consultants.

Survey your most knowledgeable colleagues to develop (and keep updated) a list of potential consultants. Think "out of the box" about consultants (i.e., those outside your institution, at a university, or in private practice). Cultivate professional relationships with such consultants to facilitate input by phone, email, or in-person meetings.

5. Plan in advance.

When treating patients with opioids it is ideal to have both a "go-to" pain specialist and an addiction specialist available if consultation becomes necessary. Unfortunately, these two types of specialists are often in short supply, and many physicians struggle to find specialists to accept their referrals. An optimal level of care, when possible, would include consultants who can assist you with your patients and continue to give you guidance after most of the patients have been returned to you for chronic treatment. If it evolves that a patient is to receive ongoing care from a consultant, this understanding should be worked out between you and the consultant, so that the patient receives clear messages and clear treatment.

6. Expect your consultant to communicate with you.

This may seem fundamental to any consultation, but problems can arise when the consultant treats your patient without communicating the treatment plan with you or fails to keep you informed as treatment progresses. This is a two-way street, of course. You must be

available to discuss the plan and progress with the consultant, as well. Often this can be done with an exchange of notes, but more immediate contact by phone and email may be most expedient and preferable.

Referral for Patient Behavior Issues

One of the more common reasons a physician may need to seek help by referral is with patients who are difficult because of their behaviors. Primary care clinicians or specialists must both maintain an alliance with their patients and set boundaries within which good healthcare can proceed and harm can be avoided. When the relationship becomes strained by constant demands or other difficulties, it can be helpful to bring in a second party, such as a pain consultant, who can offer an objective perspective and who has not yet been influenced by the patient's mixed messages or inconsistent behavior. (Effective pain management consultants should offer strategies that preserve the self-esteem of both the patient and any staff involved. They should assiduously avoid pointing blame or embarrassing the patient, physician, or staff.)

Patients dealing with chronic pain can exhibit a range of behaviors that can challenge the most poised and professional clinician. Patients in pain may have many reasons to be angry, argumentative, mistrustful, anxious, and depressed. (Depression and anxiety disorders are two-to-three times more prevalent among patients in chronic pain than in the general population.) These patients may strongly disagree with the physician's assessment or treatment and can have idiosyncratic reactions to procedures, such as a severe provocation of pain in the absence of any procedural

complication. Even the most mild-mannered and polite person can become demanding and even obnoxious under the lash of constant pain, sleep deprivation, hassles associated with working through the maze of healthcare bureaucracy, and frustration with physical limitations that make even the simplest activities, such as tying one's shoes, a struggle. They can also display destructive behaviors, such as threats of suicide, self-mutilation, extreme noncompliance with treatment, and opioid misuse.

Aberrant patient behaviors do not exist in a vacuum, of course. Sometimes the physician can weaken the relationship as well. In the pressure-cooker of daily practice, it is all too easy to lose patience, compassion, warmth, and one's sense of humor. As a result, physicians can be perceived as arrogant, uncaring, unintelligible, or rushed. In any situation involving a patient's aberrant behavior, the source of the difficulty lies either with the patient, the physician, or (most often) in a combination of personality attributes embedded in a complex set of stressful circumstances.

Managing Difficult Patient-Physician Relationships

Although referral for difficult patient behaviors is legitimate and often desirable, it is also true that physicians can work to improve their own practices and learn ways to deal early with potentially difficult situations. Ideally, we try to act well before the patient-physician relationship has degenerated to the point where referral is a means to avoid the patient. Indeed, although aberrant patient behavior is certainly challenging, successfully dealing with such behaviors can be rewarding. Most difficult behaviors will be found, upon compassionate reflection, to be rooted in

patient fear, frustration, bias, anxiety, past trauma, or simply the corrosive effects of pain, fatigue, and stress. In many ways, the patients displaying the most severe behaviors are the ones most in need of a physician's help. Disliking a patient is never comfortable, but it's important that you not deny or avoid recognizing those feelings. Self-awareness can allow you to effectively isolate the potentially harmful reactions that accompany such personal dislike. Moreover, awareness can be the tool that allows you to retain the elements of care that make your practice viable and worthwhile.

Aberrant patient behaviors, such as manipulation, verbal abuse, or hostility, may promote clinical mistakes that would never be made in typical non-threatening interactions. The most classic mistake is for a physician faced with a difficult patient to rush an examination or treatment decision in a desire to get to the next case or to prompt the patient to move on to somebody else who will take responsibility for his or her care. This is like driving in a rain storm with slippery roads and, instead of slowing down, you speed up—thinking that the faster you go, the sooner you'll be out of the storm. This is obviously a formula for disaster, either in a car or in the clinic with a challenging patient.

The only universal rule in difficult situations is to SLOW DOWN! Listen and watch more purposefully than usual. Take your own pulse—ask yourself what you are feeling and why. Check your assumptions about the case and ask whether you are being pressured to do something without justification. Perhaps you need to add a follow-up visit or a consultation with another physician before jumping into therapeutic action. A common-sense solution is usually available if you take the time to find it.

Here are some practical rules of thumb for dealing with aberrant patient behaviors:

1. **Listen reflectively.** Listen to the patient in order to determine his or her understanding of the problem, disease, or expectations from treatment, including any religious or cultural factors that might be influencing his or her beliefs. Ask questions that confirm or correct your understanding or assumptions about the case.
2. **Assume a non-confrontational stance.** Dealing with a difficult patient can easily spiral into a battle of wills or wits that will solve nothing. Try to approach patients with the assumption that you are both on the same side. If a patient says or does things you disagree with or feel are groundless, pause and then reflect back what he or she just said rather than automatically rejecting, denying, dismissing, or contradicting. This takes practice and patience. If sometimes you "lose it" and find yourself stuck in a thicket of heated emotions, step back (literally, if necessary) and collect yourself. (Don't worry, this happens to everyone sooner or later.)
3. **Avoid paternalistic interactions.** Remember that patients are in charge of their own health decisions. Rather than assuming the role as key decision-maker or all-knowing sage, physicians can help themselves and their patients by framing their role as a partner or "medical consultant." This means that the patient can choose to accept or reject physician recommendations, stay with a physician, or see someone else. This shifts responsibility and the direction of information flow from the perceived

"omnipotent" physician dictator, who is telling the patient what to do, to the "strong advisor" physician who offers realistic solutions for the client to adopt.

4. **Include the patient in planning the treatment regimen.** The largest single determinant of the success of a treatment regimen may be a patient's ability and willingness to carry it out. Patients who participate in creating their treatment plan and who understand its underlying rationale may be much more likely to adhere to it than those who are merely told what to do.
5. **Focus on the big picture.** Patients understandably focus narrowly on their pain, illness, or incapacitation and their words or actions arise from that tunnel vision. Physicians can "pull back" to see not only the present situation, but the larger life context of the patient, antecedents that might be contributing to the problem, and the path from the present pain to a future function-based goal or outcome.
6. **Set limits for acceptable behavior.** No patients, regardless of the pain they may be in, have the right to insult, verbally abuse, threaten, or physically harm a healthcare worker. At the first instance of such behavior, you can set or reinforce clear limits. In such cases, firmly and clearly establish (1) that the behavior is unacceptable, and if repeated, you will remove yourself from their care until acceptable behavior is possible; and (2) that you will have to evaluate whether ongoing care within your practice is possible. You could also turn care over to another physician in such instances, since sometimes a different personality type may work better with certain patients. But such a transfer must always be based on the patient's best interest,

with adequate transfer of records and information to assist in optimal care in the future.

7. **Maintain safety.** Keep firmly in mind that immediate safety is the first priority, and if patients threaten to harm themselves or others (including you), they may need to be physically restrained and assisted by either the police or psychiatric professionals. Maintain procedures within your office that promote easy exit from a room in which you might feel physically unsafe or develop strategies through which help can be immediately called for and received. Safety for patients, your staff, and yourself must be your highest priority. Determine in advance what rules and policies govern your institution or practice setting, and strictly adhere to any institutional policies or state laws in such cases. Educate all staff on policies and procedures, and practice your response to potential scenarios before they occur.

A specific type of difficult patient behavior that is more likely to crop up in the context of prescribing controlled substances is deception and distrust. Some patients lie, but only sometimes does a lie represent a real threat to the therapeutic relationship and the effectiveness of a treatment regimen. If you suspect a patient is lying and you feel the issue is important, you may want to deal with the issue directly. In doing this, it is again helpful to frame your role as that of a professional consultant, with the patient in charge of ultimate decision-making. Your role is not to judge or punish but to present facts and find solutions.

It can be difficult, but it is helpful to try to see lies as revealing important information about the patient. Many of us react to being lied to with offense and hurt feelings.

However, every clinician will probably be lied to from time to time. It's a "yellow light" signaling caution, and in and of itself, does not require rejection or termination. Your task is to try to find the truth without stigmatizing or harming the patient and without making yourself feel better at the expense of the patient.

Treatment Termination

Aberrant patient behaviors will occasionally require that the patient be dismissed from a practice. Physicians can, and should, have a "zero tolerance" policy for illegal behaviors (e.g., selling prescription medications, threatening violence, or forging physician signatures) or dangerous situations. Other circumstances can make "administrative termination" necessary, such as an opioid-addicted patient who refuses treatment for his or her addiction.

In such cases, abandonment must be avoided and the patient should be informed of the reasons he or she can no longer be treated by you. Such messages may occur during a face-to-face visit and followed up with a formal letter, and it may be advisable to include a witness, such as a nurse or medical assistant. In the absence of such a meeting, since face-to-face opportunities may simply be impossible, a certified letter can be used. You can specify the terms of separation (e.g., 30 days after receiving the letter, the patient will no longer be admitted to your practice). Exactly how to achieve the best result for the patient and yourself, however, will require individualization and possibly, consultation with a bioethics committee, a risk-management specialist, or an attorney.

All physicians are bound ethically not to abandon a patient in their care. Exactly how you fulfill this responsibility may also require professional consultation. In some states, there may be legal or regulatory requirements for termination of a patient-physician relationship. In many situations, you may give the patient names of other providers in his or her community or contact information for the local medical society, from which the patient can obtain a list of providers. Last, at discharge, you must consider how the patient will tolerate treatment discontinuation without harm, and, in cases involving such drugs as opioids, benzodiazepines, anticonvulsants, and antidepressants, and others, safe discontinuation may require a tapering schedule.

Summary

This chapter has discussed the common need to seek consultation from allied health professionals when dealing with patients in chronic pain. It has explored the related issue of managing the patient whose behavior has become difficult. We have seen that, although aberrant patient behavior can be difficult, it also can be potentially rewarding. Challenging behaviors usually arise from fear, frustration, poor pain control, or the corrosive effects of fatigue and stress. As such, the patients behaving "worst" are often the ones most in need of a physician's help. Working to expand self-awareness and cultivating a network of other professionals whom you can call for help can enable you to remain in control and retain the elements of care that make your practice effective for your patients and gratifying for you—even when confronted by the most difficult patients.

Chapter 6: Documentation

"The physician should keep accurate and complete records to include: the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; informed consent; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review."
–FSMB Model Policy

Documentation is important in the management of any patient, and particularly so when opioids or other controlled substances are used as part of pain management. Not only is clear, consistent, and detailed documentation part of "best practices," it also is a necessity for reliable and legitimate assessment of the effectiveness of a longitudinal treatment regimen. Although documentation is valuable as a record of one's rationale for a particular treatment regimen and offers obvious benefits and protection for the treating clinician, the focus here is on creating and maintaining a solid record because it is in the patient's best interest.

Given the impossibility of remembering the details of all your patients, a written record may be the only way to keep track and to spot trends over time, whether they be

progress toward functional goals, severity of side effects, or subtle changes in patient demeanor or affect. In the event of a need to refer a patient to a specialist, careful documentation will enable optimal continuity of care.

Everybody wins when clinical behavior and decision making are as transparent as possible.

Transparent documentation is the part of the process where a physician records as clearly as possible how the risk/benefit analysis was applied and how it played out for a particular patient. This means that, not only has the basic care plan been documented, but the decision-making process and the rationale behind specific courses of treatment also have been adequately considered. Remember that both treating and not treating involve risks. Physicians cannot avoid managing risks. Considering the risks and the contrasting benefits of any treatment is a cornerstone of clinical practice, but many of us do not emphasize this in our clinical notes. Everybody benefits when clinical behavior and decision making are as transparent as possible.

This means that not only has the basic care plan been documented, the decision-making process and the rationale behind specific courses of treatment also have been adequately communicated. Remaining focused on the risks being considered and the contrasting benefits of any treatment is a cornerstone of clinical practice, but many of us do not emphasize this in our clinical notes. Remember that both treating and not treating involve risks—physicians cannot avoid being risk managers. Transparent documentation is the part of risk management where a physician records as clearly as possible how the risk/benefit analysis was applied and how it played out for a particular patient.

Many computerized systems are now available for the acquisition, storage, integration, and presentation of medical information. Most offer advantages that will benefit both patients and physicians, because, among many other advantages, records are kept up to date and information relevant to prescribing or treatment is instantly available. In the future, even more sophisticated information systems may become available that include customized and automated patient-education and patient-assessment tools. Such systems offer the promise of greatly improving practice efficiency and patient satisfaction.

Clear documentation, however, is not dependent on computerization or electronic record-keeping; it's dependent on a commitment to achieving clear and enduring communication in a systematic fashion. Paper and pen or the dictated word still can be sufficient.

Elements of Effective Documentation

As a broad guide, six basic elements of a patient's care should be documented in writing: (1) Assessment, (2) Treatment Agreements, (3) Education, (4) Action Plans, (5) Outcomes, and (6) Monitoring.

Each clinician has to use clinical judgment to determine how often each element of documentation is required to be repeated. Each of these should at least be part of initial evaluations and considered for updating on periodic review of the case. Regardless of the system used to document clinical decisions, detailed, readily available, and transparent documentation in the patient medical record must cover a broad range of areas, including the following: (However, assessing all areas is not required at every visit and depends on patient and treatment variables.)

- Medical history and physical examination;
- Diagnostic, therapeutic, and laboratory results;
- Evaluations and consultations;
- Records of periodic reviews of patient behaviors, side effects, and functional outcomes.
- Medications (including date, type, dosage, strength, and quantity prescribed);
- Pain intensity levels;
- Levels of functioning, and quality of life;
- Subjective complaints of the patient;
- Objective findings by the physician;
- Diagnostic impressions, and potential treatment options;
- Treatment objectives
- Other specific aspects of the treatment or treatment program;
- Discussion of risks and benefits;
- Informed consent;
- Instructions and agreements; and
- Plans for periodic review of patient behaviors, side effects, and functional outcomes.

Specifics of Documenting Controlled Substance Prescriptions

Each state has laws that govern the appropriate prescribing of controlled substances and prescribers are required to know and abide by these regulations. Each state's board of medicine (titled differently by each state) oversees the professional conduct of physicians, or more precisely, the conduct of physicians who are practicing within the bounds of medicine. As such, a medical board review of a physician's practice will focus on whether or not care is delivered within or outside the

standards of care. Demonstrating whether a practice is within the standard of care usually relies to a large degree on a physician's self-generated documentation of his or her work. It will be through this documentation that reviewers assess the level of awareness of risks involved in the delivery of care and the rationale for the choices that were made. In medical practice, there are often no absolutes on the exact treatment for every patient, and physician judgment is often the mitigating variable. Therefore, understanding the elements of the physician's judgment, which is best supported through transparent documentation, may be all that a medical board investigation has to go on to judge a physician's practice. Moreover, most medical boards will consider maintenance of adequate records of patient care as a requirement in and of itself.

Federal law also governs the appropriate prescribing of controlled substances and prescribers are also required to know and abide by these regulations. The authority to prescribe Schedule II-V drugs is granted by the Federal Government through the Drug Enforcement Administration (DEA.) The DEA, which resides within the Federal Department of Justice, describes a number of specific steps that practitioners must follow to document the use of controlled substances. These procedures may, or may not, correspond with state-specific standards. Each practitioner, therefore, must fully understand his or her state rules as well as follow the DEA requirements.

A revised DEA practitioner's manual was introduced in September 2006 and is available online at www.deadiversion.usdoj.gov. It summarizes and explains the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA) and

the Code of Federal Regulations. Although all prescribers of controlled substances must know these federal requirements, a complete review is beyond the scope of this book. The Appendix includes links to relevant DEA websites, including the 2006 DEA Practitioner's Manual. Excerpts from that manual that relate to general aspects of prescribing controlled substances, including requirements for appropriate documentation, are posted on FSMB's website: www.fsmb.org/pain.

Accurate Coding

Nowhere are information systems more detailed and often idiosyncratic than in the area of communicating with payers for authorization and billing. Although learning the details of these requirements can be formidable, physicians who fail to adequately conform to a documentation system can compromise both the overall efficiency of the system and the care their patients receive. Documentation requirements and procedures may vary considerably across institutions, and across administrative or reimbursement systems within a single institution or practice.

Documentation for coding purposes is often compromised by providing inadequate specific information to accompany a code or assuming that the person reading the document (often a non-medically trained "coder") understands the implications of examination results or other details of the history or treatment plan. It has become an all-too-apparent reality that coders are limited in what they can code, and physicians must understand basic documentation requirements for coding. Coders are not allowed to "interpret" and must depend on the quality of the documentation in the medical record. For instance, if a physi-

cian writes that the patient has a hemoglobin of 5.0 in the medical record, the coder cannot interpret this as anemia, even if he or she knows enough to suspect this finding. In order to code it, the physician must specifically document anemia in the record—in this case example, there might also be a need for additional information such as other specifics around the type of anemia and its relationship to other comorbid diagnoses that may impact the accuracy of coding assignment. In general, physicians should document their suspicions to the highest degree known, yet another example of the benefits of transparency.

Proportionate Prescribing

At times, prescribers may feel inclined to assist their patients by prescribing more doses of a scheduled drug than the patient may need to manage an acute pain condition. This is particularly the case for schedule III medications such as hydrocodone or schedule II drugs such as oxycodone.

For example, a patient with an acute backache might be anticipated to need hydrocodone with acetaminophen several times over several days. In some cases, this might amount to a maximum of eight tablets per day over two to three days, perhaps for a maximum of five days. Pain lasting beyond this period might suggest that the patient should be re-evaluated. Although the total anticipated need would add up to a maximum of 40 tablets, physicians too commonly write a prescription for 90 to 150 tablets, perhaps with a few refills, innocently believing it is in the patient's interest to have more on hand if pain persists.

However, in the current environment where prescription opioids are increasingly diverted or abused—sometimes

from households where medicine cabinets with leftover medication are accessible to children, teenagers, and others—vigilance is required more than ever. This includes tailoring the amount of a scheduled drug to a reasonable assessment of how much you think your patient will need.

Some physicians may consider a schedule III drug such as hydrocodone to be relatively safe, unaware that hydrocodone is the most prescribed medication in the United States[1] and is widely sought after and diverted for nonmedical purposes. Regulators recognize that medical judgment is not a science but is nonetheless required for optimal clinical efficacy and overall safety—and this includes prescribing appropriate amounts and refills that are proportionate to expected clinical outcomes.

Summary

Although it comes near the end of the list of guidelines in the FSMB *Model Policy*, documentation is an essential component at every step of the process of delivering appropriate pain care. Effective documentation is vital to supporting all of the other elements of the FSMB *Model Policy*. Moreover, complete documentation is essential to indicate compliance with state and federal laws that govern prescribing controlled substances. Last, documentation is required for supporting coding, billing, and reimbursements.

References

1. Kuehn, B.M. Opioid Prescriptions Soar: Increase in Legitimate Use as Well as Abuse. *J. Amer. Med. Assoc.*, 2007, 297(3):249-251.

Chapter 7: Compliance With Relevant Law

"To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations."
–FSMB Model Policy

As useful as they may be, opioid medications are scheduled as controlled substances because they also have a potential for abuse. Consequently, they and the healthcare professionals who prescribe, administer, or dispense them are regulated by a complex series of federal and state policies on controlled substances, as well as other state laws and regulations that govern healthcare practice. Such policies are intended to prevent drug abuse and substandard prescribing practice. But in some cases, they can have impact that goes beyond their intended purpose in ways that can hamper legitimate medical practices and create barriers for caregivers and patients.[1]

Although considerable progress has been made in the past decade to amend state laws in hopes of striking balanced regulatory policies, significant state-to-state inconsistencies remain. Some state policies may create particular

practice standards that differ from national conventions. Growing attention to the separate public health crises of undertreated pain and prescription drug abuse are leading to calls for more circumspect and specific regulations. Some state laws have been recently revised or are in the process of revision. In some states, however, there still may be legal language in the professional and business codes that could raise concerns by:

- Limiting the amounts of opioids that can be prescribed and dispensed;
- Requiring special government-issued prescription forms;
- Restricting access to patients in pain who have a history of substance abuse or addictive disease;
- Using antiquated and ambiguous language that can confuse patients in pain with people who have addictive disease; or
- Requiring opioids to be only a treatment of last resort.

Language that can enhance pain management is now frequently being added to state policies and laws. However, there remain some states in which the need for appropriate pain care is not well articulated. For example, some states do not recognize that controlled substances are necessary in some cases, or that pain management is an integral part of the practice of medicine.

It is imperative that physicians are thoroughly familiar with their own state's laws and regulatory practice standards. (Access to these laws, or summaries of the laws, is available through the Federation of State Medical Boards website: www.fsmb.org/pain.) Unfortunately, evidence suggests that many physicians remain ignorant of the state regulations under which they practice. This may have divergent consequences: On the one hand, some physicians may limit their use of controlled substances in the mistaken belief that their state laws are restrictive or overly punitive; on the other hand, some physicians may be practicing in a manner inconsistent with accepted standards and this might be viewed as potentially suspicious by their state's regulatory agencies that oversee medical practice.

Physicians also must have a firm grasp of the federal laws relating to controlled substances. These laws are articulated in the federal Controlled Substances Act (CSA), which attempts to balance the competing demands of both control and availability. Under this act, licensed professionals can prescribe, dispense, and administer controlled substances for legitimate medical purposes in the course of professional practice. (Note that most opioid analgesics are Schedule II drugs although a few, which happen to be the most prescribed, are schedule III drugs—Schedule I drugs such as heroin and LSD are considered to have no legitimate medical uses.) The "control" portion of the CSA attempts to prevent diversion, establishes a system of secure manufacture and distribution, requires record-keeping procedures, and sets up penalties (including criminal prosecution) for violating its provisions.

Prescription Monitoring Programs

In response to the problems of drug diversion and abuse of prescription medications, the Federal Government and many states have promoted prescription monitoring programs (PMPs). Typically, PMPs collect prescribing and dispensing data from pharmacies, conduct reviews and analyses of the

data, and disseminate the data to appropriate regulatory and law enforcement agencies. Some have begun to make these data available to clinicians and a few have even made the data readily available at the point of care. It seems certain that more states will be moving in this direction in the future.

Following the lead of New York State in the 1910s, California and Hawaii enacted PMPs in the 1940s. By the 1980s, seven more states had added PMPs. These early programs required that physicians use state-issued multiple copy forms (duplicate or triplicate) to write prescriptions for Schedule II controlled substances, and that pharmacies return one copy to the state after dispensing a drug. Physicians were usually required to obtain prescription forms from a state law enforcement agency and some states charged a fee for the forms or limited the amount that could be ordered at any time.

Only one multiple copy prescription program still exists because of the barriers to care that most caused, as well as the advent of technological solutions that use computerized information systems to take the burden of prescription monitoring away from the front lines of clinical care. Most states are now moving to computerized PMPs. In such systems, pharmacies transmit data to the state on controlled substances prescriptions. Although there is currently a federal program that supports individual states in their efforts to implement a PMP (National All Schedules Prescription Electronic Reporting Act of 2005), in practice, PMPs take different forms because each state government is charged with determining the goals, structure, and organization of its

program. Variation between states is still common, even in states that border each other and must deal with patients crossing state lines for care.

Certain characteristics of PMPs can have a deterrent effect on potential criminal activities. For example, some state authorities report that use of tamper-resistant prescription forms significantly reduces or eliminates prescription forgery. Thus, while government-issued serialized prescriptions have largely been abandoned as useful tools for prescription monitoring, the use of security paper that is tamper-resistant is increasing. These security-paper prescription forms employ the same technology that has long been used on personal bank checks or on paper money—these include a watermark that may be viewed at a certain angle, photochromic features that produce an image such as the word "void" if the paper is copied or scanned by a light source, or even thermochromic features in which the paper changes color when touched by warm fingers or a heat source. In addition, PMPs that make prescribing information available to clinicians at the point of clinical care may be useful for identifying "doctor shopping." An individual who is identified as doctor shopping should have his or her treatment plan re-evaluated, may need additional guidance and education, may be directed into treatment for chemical dependency, or may be prosecuted, depending on the circumstances of the case.

To date, not all PMPs have been created equal, however, and some may have inadvertently erected barriers, either overt or implicit, to the appropriate prescribing of opioids for legitimate medical purposes.[4] Some programs may have sent unintended and subtle messages to physicians that

encourage them to be stingy with or paranoid about prescribing strong pain medicines. Data show that physicians recognize such messages and alter their practices accordingly, often with detrimental results. For instance, California had the oldest PMP system in the United States, which used serialized triplicate prescriptions solely for Schedule II drugs. On several occasions, pain-care advocates tried to convince the California legislature to rescind the triplicate program as it was widely believed to be a barrier to adequate pain management. On each occasion, arguments were made that if California removed its triplicate-based PMP, it would see markedly increased Schedule II prescribing, which often provides optimal treatment for patients with severe chronic pain, but also increases abuse of these medications. The assumption was that maintaining low levels of Schedule II drug prescribing was protecting citizens from drug abuse. The triplicate PMP was ultimately removed when the legislature was able to see that while the triplicate PMP clearly resulted in low Schedule II prescribing, including low prescribing rates of sustained release oxycodone, California had a disproportionately high rate of Schedule III opioid prescribing and abuse, particularly hydrocodone (found in products compounded with acetaminophen such as Vicodin, Norco, Lortab, etc.) Ironically, hydrocodone is the most prescribed drug in the United States, prescribed in far greater numbers than any other opioid.

The California experience was predictable. It is well-established that when physicians are faced with barriers to prescribing a certain type of medication, they will often prescribe around that barrier, turning instead to drugs that are perceived to be less scrutinized, even if they are less efficacious and/or potentially harmful. This pattern is known as the substitution effect.[5] The problem of the substitution effect is one example of how we may view a set of data relating to the drug abuse problem and draw conclusions that neither factors in all of the relevant variables nor anticipates the full collateral impact on the drug-abusing population or on patients with a legitimate need for controlled substances.

Contemporary PMPs are not intended to interfere with medical practice, and attempts are increasingly being designed to reduce potential barriers to care. Unlike PMP programs of the past that were intrusive at the point of clinical care, newer electronic-based PMPs collect data behind the scenes of clinical care. Likewise, contemporary PMPs typically do not require physicians to obtain prior approval to issue prescriptions and they do not impose limits on the quantity that may be prescribed. Limitations on prescribing controlled substances do exist, but are governed by laws that are separate from those related to PMPs. For instance, federal law prohibits prescribing refills on Schedule II drugs, and recently the DEA has made adjustments to exactly what constitutes a refill. Likewise, some state laws may limit quantities that can be prescribed in one prescription, but such limitations are completely distinct from the individual state's PMP.

More states are likely to institute PMPs in the future because of the 2005 congressional approval of the National All Schedules Prescription Electronic Reporting Act (NASPER). This law instituted a program that offers individual states funding for establishing PMPs. Although NASPER was hailed as a major tool for clinicians, it did not mandate that the collected information would be directly available to physicians at the time that they treat

their patients. However, PMP data should and likely will be more available to clinicians at the point of care. Using these data may prove to be increasingly important in the management of patients who use controlled substances.

Federal Guidelines for Prescribing Controlled Substances

As noted in Chapter 6, the DEA released an updated Practitioner's Manual in September 2006. It summarizes and explains the basic requirements for prescribing, administering, and dispensing controlled substances under the CSA. The complete manual is available online (www.deadiversion.usdoj.gov) and physicians are urged to read it carefully. This internet website is also of value for any updates that may occur. Moreover, the DEA also issued a clarification of its policies relating to the use of controlled substances for pain that appeared in the September 6, 2006 Federal Register (Vol. 71, No. #52716- 52723, 172, 21 CFR Part 1306.) This document is titled Dispensing Controlled Substances for the Treatment of Pain. Select passages that are posted on www.fsmb.org/pain offer DEA clarification on the following topics:

- Purposes and Structure of This Document
- The Statutory Role of DEA in Regulating the Prescribing of Controlled Substances
- The Meaning of the "Legitimate Medical Purpose" Requirement
- Other Recurring Questions
  - ☐ What are the potential signs to a physician that a patient might be seeking drugs for the purpose of abuse or diversion?

  - ☐ What are the general legal responsibilities of a physician to prevent diversion and abuse when prescribing controlled substances?
  - ☐ What additional precaution should be taken when a patient has a history of drug abuse?

In the fall of 2007, the DEA also issued a final ruling [Issuance of Multiple Prescriptions for Schedule II Controlled Substances in the Federal Register: November 19, 2007 (Volume 72, Number 222,Page 64921-64930)] that amends its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same schedule II controlled substance. These multiple prescriptions allow a physician to write, and a patient to receive, sequential prescriptions for up to a 90-day supply of that controlled substance. Thus practitioners may write multiple prescriptions, each dated the day the prescriptions are written, but only one would be for immediate filling while the others would have sequential and non-overlapping fill dates. The intervals are up to the prescriber so that it might be days, weeks or months. For instance, a prescriber might state "do not fill until 30 days from prescription date" or "do not fill until 60 days from prescription date", etc.

Summary

Current federal regulations, emerging state laws, and in particular, the FSMB *Model Policy* seek a rational balance that supports society's need to be protected from drug abuse and to receive effective treatment for pain. Physicians who find such balance in their practice will likely find themselves congruent with the goals of regulators and, most important, with

the needs of their patients. New or revised regulations, and the reality of changing or inconsistent existing regulations at both federal and state levels, reinforce the fundamental message of this chapter and the FSMB *Model Policy*: physicians must take the time to educate themselves about the realities of the legal environment in which they practice and remain up to date on any changes to those policies. Doing so will facilitate best clinical practices in terms of pain management and will reduce the chances for practice disruption through inadvertent intrusion by the legal system.

References

1. Pain and Policy Studies Group. *Achieving Balance in State Pain Policy: A Progress Report Card.* University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin, Sept. 2003.

2. Joranson, D.D., et al. Pain Management and Prescription Monitoring. *J. Pain and Symptom Management,* 2002, 23(issue):231-238. (see p. 12, no. 3)

3. Fishman, S.M., et al. Regulating Opioid Prescribing Through Balanced Prescription Monitoring Programs. *Pain Medicine,* 2004, 5(2):255-257.

4. Fishman, S. The politics of pain and its impact on pain medicine. *Pain Medicine,* 2005, 6(3):199-200.

5. Fishman, S.M. Commentary: Prescription drug abuse and safe pain management. *Pharmacoepidemiology and Drug Safety,* July 24, 2006, vol(issue):page nos. (see p. 12, no. 1)

Overview: A Capsule Summary of Steps You Can Take Today

This book and the updated resources on the FSMB's website offer a pragmatic framework for treating pain with compassion and vigilance. I hope it adds to your confidence to practice medicine by seeking to cure when possible, but to always treat suffering.

The steps that are stressed in these chapters should not impose new burdens, because the approaches, procedures, and mindset advocated in the *Model Policy* articulate the standards that are essential components of sound medical care that physicians strive to achieve every day. Putting the *Model Policy* to work, therefore, is more a matter of reframing one's approach than adopting an entirely new way of practice. However, many of these steps will be difficult to attain on a daily basis in a busy general practice without increasing your knowledge base about pain management and developing simple, skills, tools, and procedures that will expedite the process.

This will not be an onerous addition to your work if you prepare in advance for the education and monitoring needs of your patients who require controlled substances and refine your general knowledge base and skills around assessment and documentation. And once accomplished, the principles and practices discussed in this book will enhance your clinical operation well beyond prescribing controlled substances.

Below is a capsule summary of the steps you can take right now to integrate the tenets of the *Model Policy* into your day-to-day practice:

1. Patient Evaluation

- Make time to listen carefully to patients in pain.
- Use a reflective listening approach.
- Remain mindful of the need for suspicion without a rush to judgment.
- Look for signs of abuse, but recognize the complexities of presentation and the possibilities of pseudoaddiction.
- Remember that not treating pain is often not a "safe" option.

2. Treatment Plan

- Use a function-based paradigm at diagnosis and follow through with a function-based treatment plan.
- Develop a list of functional losses and gains that will be impacted by care, then track and modify them throughout care.
- Simply "feeling better," without improving functioning in some aspect of an individual's life, may not reflect improvement in quality of life.
- Modest reductions in pain score may actually be extremely significant in terms of reclaimed function.

3. Informed Consent and Agreement for Treatment

- Patients must fully understand the potential risks and benefits of any procedure or treatment to be truly "informed" as required by both law and medical ethics.
- Regardless of whether or not you are prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent process.
- Prepare the educational materials and other documents that you will need in advance and develop in advance an efficient process for implementing these steps for all of your patients—much of which can take place outside of your exam room. (See Appendix A for online educational resources you can download and use in your practice.)
- A written agreement/informed consent process can help addresses the key points of the *Model Policy* (Go to www.fsmb.org/pain for more information about agreements and sample agreements that you can adapt to the needs of your patients and practice.)

4. Periodic Review

- As in all treatments, including those involving controlled substances, physicians must closely attend to treatment outcomes and be alert to a wide range of potential adverse effects.
- Monitoring progress toward a set of functional goals requires a means of measuring progress (or lack thereof), which must be clearly documented from the start of treatment.
- The responsibility of attaining treatment goals and presenting supporting evidence lies with the patient.
- Assess functional goals and move the "goalposts" as needed.

5. Referral and Patient Management

- Build a network of clinical experts to whom you can turn for specialized needs.

- Be clear with yourself about the breadth and depth of your expertise, and don't hesitate to refer patients at the earliest signs they may need help.
- Remember that patients in pain can appear "difficult," but that the most "difficult" patients are often the ones who most desperately need your help.

6. Documentation

- Documentation is an essential component at every step of the process of delivering pain care.
- Document assessments, treatment agreements, education; action plans, and patient monitoring activities.
- Be clear about why you are taking risks and your plan for risk management. Transparency as to your reasoning about risk management decision-making is a critical component of documentation.
- Include enough specific information that a person reading the document understands the implications of exam results or other details of the history or treatment plan.

7. Compliance With Controlled Substance Laws and Regulations

- Know your state regulations on controlled substances and adhere strictly to them.
- Be familiar with and adhere to all relevant Federal regulations.
- Access to relevant state and federal laws is available through the Federation of State Medical Boards website: www.fsmb.org/pain.

Conclusion: Balancing Vigilance and Compassion

As the preceding chapters demonstrate, the FSMB *Model Policy* focuses on process-oriented aspects of patient care, leaving selection of drug, dose, duration, etc. well within the bounds of each physician's clinical judgment. These principles are presented as a basic framework for an organized, systematic medical practice. They offer substantial latitude and flexibility, allowing practitioners to deviate from these steps if, in their reasoned judgment, it's in the best medical interest of a patient.

By incorporating this framework, you can take comfort in knowing that, although heightened concern about controlled substances may remain among clinicians and regulators, practicing in accord with the FSMB *Model Policy* squarely aligns you with adherence to basic tenants of well-established medical practices. Perhaps more important, adhering to the tenants of the *Model Policy* not only facilitates appropriate treatment of pain with controlled substances, but also supports a healthy overall practice.

That is the backdrop against which this book and the *Model Policy* were conceived: Delivering optimal care to patients in pain. The patient is the ultimate beneficiary of therapeutic pharmacovigilance. As we treat patients in pain, it is all too easy to lose sight of these goals, particularly in an atmosphere of legitimate concerns over abuse

and diversion. It is vitally important that the best interest of the patient and society always remain in the foreground.

As the FSMB *Model Policy* emphasizes, opioid analgesics are legitimate and effective agents for pain control. Nonetheless, they are not always indicated or appropriate. As always, clinicians must base their decisions to use or withhold opioids on a case-by-case risk/benefit analysis, keeping in mind that there are substantial risks associated with ignoring pain. As described in its introduction, the FSMB *Model Policy* is a tool that medical boards and other regulators use to assess whether your practice is within the standard of care. Thus, a practice consistent with the tenets of the *Model Policy* should be positively viewed by regulators. This may reduce the hesitation—or even paralysis—that some practitioners now feel about prescribing controlled substances.

The fundamental tenets of responsible opioid prescribing for pain—complete evaluation, balanced risk-management, and transparent documentation—are the pillars of any functional medical practice, particularly in pain management. In the often murky realm of pain assessment and treatment, trust and transparency are paramount within the therapeutic relationship. Therefore, I cleave to the Russian proverb that Ronald Reagan liked to quote: "Trust, but verify." Maintaining clinical vigilance is critically important in all domains of medical practice and is particularly important for patients in pain who are at increased risk of a host of complex collateral consequences. These include an array of manifestations of physical as well as psychological deconditioning, such as fatigue, insomnia, depression, anxiety, and even suicide. Some patients may also be at risk for

addiction. By establishing a clear framework for assessing, treating, and tracking patients, we improve our odds of achieving an optimal therapeutic outcome.

The FSMB *Model Policy* does not set a standard of medical practice. These details of care require medical knowledge and information about a patient that can only be determined through the deliberate and individualized clinical judgment of the treating physician. Since few generalizable treatment algorithms exist, regulators should recognize—as I believe they do—that society is best served by prudent risk-conscious practitioners who apply their best judgment, based on individual characteristics that vary greatly from patient to patient.

Physicians are given great latitude in judgment when risks are managed with rational and systematic care. This involves treatment choices that are made with circumspect consideration of past and ongoing case details, a reasonable breadth of diagnostic expertise and treatment options, and vigilant attention to treatment goals and outcomes—all of which are clearly and transparently documented. With no single accepted method for comprehensive assessment and monitoring, physicians must use their knowledge and judgment to determine a best plan for each individual patient. This may include global policies and procedures applied to all patients in your practice, or used on a case-by-case basis. Just as in managing risk in any other treatment setting, the foundation for success rests on knowledge, concern, awareness, and proactive initiative. And as with all aspects of medical care, whenever risk is decreased, barriers to initiating interventions are lowered and chances for beneficial outcomes rise. Managing risks and benefits is

at the core of what we physicians do with all our patients; vigilance in pain management is nothing more or less than effective risk management.

Obviously, physicians must remain current not only with new developments in medicine, but also with related changes in state and federal laws. To this end, the Federation of State Medical Boards is posting updated information relevant to opioid prescribers on its website at www.fsmb.org/pain. Amongst many valuable resources, this site includes:

- Updated prescribing standards for each state;
- Links to updated information about the DEA's requirements for prescribing controlled substances; and
- Links to SAMHSA, FDA, and other government websites where you can find updated information and warnings about prescription medications.

In addition to providing resources for pharmacovigilant practice, the FSMB site also offers links to useful online pain management resources. Though most of us are called upon to treat patients in pain, few physicians have been given a full set of resources to respond to these patients' special needs. I believe that the reason many doctors resist treating pain is not that they lack compassion, are unwilling to engage with difficult cases, or that they shy away from potential legal and regulatory hassles. It is because, in the past, medicine has not made pain care a priority, and consequently most physicians are not well-trained or well-equipped to manage pain.

Pain Medicine is a young discipline that is still barely represented in medical school curricula or residency pro-

grams. Continuing medical education in pain management is largely sponsored by industry, and its quality and practicality often is hit-or-miss. We are unlikely to succeed in reversing the problem of undertreated pain without increasing education and support for physicians at all levels of training—not just in pain management, but also in drug abuse, addiction, and rational approaches to a functional practice that balances compassionate care with appropriate pharmacovigilance.

Meanwhile, the science and technology of pain medicine is expanding at a rapid rate, encompassing pain physiology, medications, procedures, devices, and other therapies. Each of us has a responsibility to attain a basic working understanding of pain management, and if one chooses to prescribe opioids or other controlled substances, a clear understanding of safe and effective prescribing practices.

Obviously, the content of this book cannot substitute for the commitment to relieve suffering. The tenets of the FSMB *Model Policy*, or any consensus practice guidelines, are only useful in service to conscientious pain management. There is no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades. The cost of undertreated pain in dollars is astronomical, but the cost in human suffering is immeasurable. Turning away from patients in pain simply is not an option.

Appendix A: Resources for Pharmacovigilance and Pain Management

The FSMB's wesite at www.fsmb.org/pain can serve as a first stop destination for up-to-date resources for pharmacoviglance in pain management. On this site you'll find:

- The FSMB *Model Policy* for the Use of Controlled Substances for the Treatment of Pain
- Updated state-by-state prescribing guidelines for the use of controlled substances, as well as other relevant state-based regulations
- Links to websites at the Substance Abuse and Mental health Services Administration, Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) where you'll find updated information about drug safety and pharmacovigilance

In addition to staying current with state and federal regulations governing controlled substance prescribing, it's also important to stay abreast of safe and effective pain management. As with any job, effectively treating patients in chronic pain is easier when you use the right tools. I'm talking here about assessment instruments, scales for quantifying pain, intake questionnaires, patient education handouts, and well-crafted doctor/patient agreements. Many versions of these kinds of tools are available for downloading from the

Internet. Below I've listed the sites I can recommend to you—and I've marked my most highly recommended sites with a ✪. I've also listed some books about pain and pain management that you or your patients might find helpful.

1. **Federal Government Resources**
2. **Medical Specialty Society Sites**
3. **Nonprofit Pain Organizations (and other sites of interest to medical professionals)**
4. **Treatment Guidelines**
5. **Pain and Function Assessment Tools**
6. **Commercially Sponsored Sites Offering Useful Clinical Tools**
7. **Medical Journals Focusing on Pain**
8. **Sites with Educational Information for Consumers**
9. **Professional and Patient Sites by Disorder**
10. **Pain-Related Books**

1. FEDERAL GOVERNMENT RESOURCES

Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov/

- National Survey on Drug Use and Health: Nonmedical Users of Pain Relievers, Characteristics of Recent Initiates: www.oas.samhsa.gov/2k6/pain/pain.cfm
- NonMedical Use of Pain Relievers: www.oas.samhsa.gov/subState2k6/agePain.htm
- Directory of drug and alcohol abuse treatment programs: http://findtreatment.samhsa.gov

Drug Enforcement Administration (DEA): www.usdoj.gov/dea/index.htm

- Drug Scheduling: www.usdoj.gov/dea/pubs/scheduling.html
- Drug Information: www.usdoj.gov/dea/concern/concern.htm
- Diversion Control: www.deadiversion.usdoj.gov/
- DEA Practioners Manual: www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html
- Survey of State Prescription Monitoring Programs: www.deadiversion.usdoj.gov/pubs/program/ijis_pmix_survey20070204.pdf

The U.S. Food and Drug Administration (FDA): www.fda.gov

The National Institute on Drug Abuse (NIDA): www.drugabuse.gov

- Prescription Drug Abuse Chart: www.drugabuse.gov/DrugPages/PrescripDrugsChart.html

The Office of National Drug Control Policy: www.whitehousedrugpolicy.gov

- The President's National Drug Control Strategy: www.whitehousedrugpolicy.gov/publications/policy/ndcs07/

2. MEDICAL SPECIALTY SOCIETY SITES

American Academy of Orofacial Pain
www.aaop.org
19 Mantua Road
Mount Royal, NJ 08061
856-423-3629
Fax: 856-423-3420

The American Academy of Pain Medicine
www.painmed.org
4700 W. Lake Ave.
Glenview, IL 60025
847-375-4731
Fax: 847-375-4777

American Medical Association
www.ama-assn.org
515 N. State Street
Chicago, IL 60610
800-621-8335

American Pain Society (APS)
www.ampainsoc.org
4700 W. Lake Ave.
Glenview, IL 60025
847-375-4715
Fax: 877-734-8758
A multidisciplinary organization of basic and clinical scientists, practicing clinicians, policy analysts, and others. The mission of the APS is to advance pain-related research, education, treatment, and professional practice.

American Psychological Association
www.apa.org
750 First Street, NE
Washington, DC 20002
800-374-2721
Offers referrals, assistance, and resources for coping with the psychological aspects of trauma and terrorism.

American Society of Addiction Medicine
www.asam.org
Email@asam.org
4601 North Park Ave, Arcade Suite 101
Chevy Chase, MD 20815
301-656-3920
Fax: 301-656-3815

American Society for Pain Management Nursing
www.aspmn.org
P.O. Box 15473
Lenexa, KS 66285-5473
888-34-ASPMN (342-7766) or 913-895-4606
Fax: 913-895-4652
ASPMN advances optimal nursing care for people affected by pain by promoting best nursing practice through educational resources, such as its peer-reviewed journal, *Pain Management Nursing*, at www.painmanagementnursing.org.

3. NONPROFIT PAIN ORGANIZATIONS (and other sites of interest to medical professionals)

Alliance of State Pain Initiatives
www.aspi.wisc.edu
1300 University Avenue, Room 4720
Madison, WI 53706
608-265-4013
Fax: 608-265-4014

American Council for Headache Education
www.achenet.org
19 Mantua Road
Mt. Royal, NJ 08061
856-423-0258, or 800-255-ACHE (255-2243)
Fax: 856-423-0082

AMA Pain Management: The Online Series
www.ama-cmeonline.com
Web-based Continuing Medical Education program on pain management from the American Medical Association

Arthritis Foundation
www.arthritis.org
help@arthritis.org
1330 West Peachtree Street
Suite 100
Atlanta, GA 30309
800-568-4045, or 404-872-7100, or 404-965-7888
Fax: 404-872-0457

City of Hope Pain/Palliative Care Resource Center
www.cityofhope.org/prc/
City of Hope Pain/Palliative Care Resource Center
1500 East Duarte Road
Duarte, CA 91010
A clearinghouse of resources to enable individuals and institutions to improve the quality of pain management delivery.

The Cochrane Collaboration
www.cochrane.org
A wide-ranging collection of evidence-based reviews including topic in pain management.

Fibromyalgia Network
www.fmnetnews.com
Educational materials on fibromyalgia syndrome (FMS) and chronic fatigue syndrome (CFS).

International Association for the Study of Pain
www.iasp-pain.org
The leading international society of multidisciplinary pain professionals; its website offers many valuable resources for professionals.

National Consensus Project for Quality Palliative Care
www.nationalconsensusproject.org
A collaborative project of the American Academy of Hospice and Palliative Medicine, Hospice and Palliative Nurses Association, and the National Hospice and Palliative Care Organization to promote the implementation of Clinical Practice Guidelines for new and existing palliative care services.

National Institute of Dental and Craniofacial Research (NIDCR)
www.nidcr.nih.gov
nidcrinfo@mail.nih.gov
National Institutes of Health, DHHS
31 Center Drive, Room 5B-55
Bethesda, MD 20892

National Headache Foundation
www.headaches.org
info@headaches.org
312-274-2650, or 888-NHF-5552 (643-5552)
Fax: 312-640-9049
820 N. Orleans
Suite 217
Chicago, IL 60610-3132

UCLA History of Pain Project: The John C. Liebskind History of Pain Collection
www.library.ucla.edu/libraries/biomed/his/pain.html
The most exstensive resource on the history of Pain Medicine.

✪ **Pain and Policy Studies Group**
www.medsch.wisc.edu/painpolicy/
The leading resource for pain-related public policy and legislative issues.

4. TREATMENT CONSENSUS STATEMENTS, GUIDES, AND GUIDELINES

✪ **Model Policy for the Use of Controlled Substances for the Treatment of Pain**
www.fsmb.org/grpol_policydocs.html
Federation of State Medical Boards
Offers clear guidance on standards for controlled substance prescribing.

The Use of Opioids for the Treatment of Chronic Pain
www.asam.org
www.painmed.org
Consensus statement by American Pain Society, American Academy of Pain Medicine, American Society of Addiction Medicine.

JCAHO Pain Management Standards
www.jcrinc.com

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction
www.kap.samhsa.gov/products/tools/keys/pdfs/KK_40.pdf
Substance Abuse and Mental Health Services Administration (SAMHSA)

World Health Organization Cancer Pain Relief: Guide to Opioid Availability
www.who.int/cancer/publications/en/
World Health Organization

Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain
www.ampainsoc.org
American Pain Society

Definitions Related to the Use of Opioids for the Treatment of Pain
www.asam.org/pain/definitions2.pdf
American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine

5. PAIN AND FUNCTION ASSESSMENT TOOLS

The assessment tools below are widely available online for downloading in various formats, including at several of the commercially sponsored sites described in the following section.

Initial Pain Assessment Tool
www3.mdanderson.org/depts/prg/bpi.htm
A charting form that can be used on the patient's initial admission to document location, intensity, quality of pain, and relief.

Brief Pain Inventory (BPI)
www.cityofhope.org/prc/pdf/BPI%20Short%20Version.pdf
A brief, simple, and easy to use tool for the assessment of pain in both clinical and research settings. The BPI uses simple numeric rating scales from 0 to 10 that are easy to understand and easy to translate into other languages. It is a well-validated instrument to measure pain intensity, functionality, and the impact of pain on one's life in the past 24 hours and within the past week.

McGill Pain Questionnaire
www.cityofhope.org/prc/pdf/McGill%20Pain%20Questionnaire.pdf
A 20-item scale that allows patients to articulate ranges of pain sensation, both internal and external.

Visual Analog Scale
www.ndhcri.org/pain/Tools/Visual_Analog_Pain_Scale.pdf
A linear scale from Worst Imaginable Pain to No Pain. Patients place a mark along the line to indicate their current pain level.

Wong-Baker FACES Pain Rating Scale
www3.us.elsevierhealth.com/WOW/
A scale that employs pictures of faces, ranging from happy to sad to assess pain in children; while designed to assess pain in children; it is also used to assess pain in adults.

6. COMMERCIALLY SPONSORED SITES OFFERING USEFUL CLINICAL TOOLS

Many of the clinical tools described in this book are available at one or more of these commercially sponsored pain management sites.

Emerging Solutions in Pain Management
www.emergingsolutionsinpain.com
A diverse collection of practical tools and resources for clinical pain management.
Sponsored by Cephalon.

National Pain Education Council™ (NPEC)
www.npecweb.org
A compendium of online CME, clinical tools, and other pain management reference sources.
Supported by Ortho-McNeil.

Pain.com
www.pain.com
Clearinghouse for chronic pain management resources, including breakthrough pain and cancer pain.
Sponsored by Purdue Pharma L.P. and Cephalon.

PainBalance.org
www.PainBalance.org
An educational site featuring physician and patient resources that emphasize the balance between safe and effective pain management and opioid abuse.
Sponsored by Alpharma Pharmaceuticals LLC.

PainEDU.org
www.painedu.org
An online resource for clinically relevant information about pain assessment and management.
Supported by Endo.

Partners Against Pain
www.partnersagainstpain.com
An informational site for patients, health professionals, and physicians.
Supported by Purdue Pharma L.P.

Legal Side of Pain
www.legalsideofpain.com
Free and subscription based information on legal issues related to pain.

7. MEDICAL JOURNALS FOCUSING ON PAIN

Headache: The Journal of Head and Face Pain
American Headache Society
www.blackwellpublishing.com/journal.asp?ref=0017-8748

Journal of Pain
American Pain Society
http://journals.elsevierhealth.com/periodicals/yjpai

Journal of Pain and Symptom Management Pain
www.elsevier.com/homepage/sah/pain/menu.html

Journal of Pain & Palliative Care Pharmacotherapy
www.haworthpress.com/store/product.asp?sku=J354

Pain
International Association for the Study of Pain
www.sciencedirect.com/pain

Pain Medicine
American Academy of Pain Medicine
www.blackwellpublishing.com/journal.asp?ref=1526-2375&site=1

8. SITES WITH EDUCATIONAL INFORMATION FOR CONSUMERS

American Pain Foundation
www.painfoundation.org
info@painfoundation.org
201 North Charles Street, Suite 710
Baltimore, MD 21201-4111
888-615-PAIN (7246)
Fax: 410-385-1832
An excellent source for patient information and advocacy with extensive links to further information as well as monitored chat rooms for consumers.

National Pain Foundation (NPF)
www.nationalpainfoundation.org
aardrup@nationalpainfoundation.org
300 E Hampden Avenue, Suite 100
Englewood, CO 80113
A comprehensive online education and support community for pain patients and their families.

9. PROFESSIONAL AND PATIENT SITES BY DISORDER

ADDICTION

American Society of Addiction Medicine (ASAM)
www.asam.org/

National Institute on Drug Abuse
www.nida.nih.gov

ARTHRITIS

Arthritis Foundation
www.arthritis.org

Medical College of Wisconsin/Arthritis
healthlink.mcw.edu/arthritis/

Mayo Clinic Arthritis Center
www.mayoclinic.com/health/arthritis/AR99999

BACK AND SPINE PAIN

Spine Health
www.spine-health.com

Spine Universe
www.spineuniverse.com

CANCER PAIN

American Cancer Society
www.cancer.org

Cancer Pain Control:
www.WHOcancerpain.wisc.edu

The Cancer Pain Education Resource (CAPER)
www.caper.tufts.edu

City of Hope Pain/Palliative Care Resource Center
www.cityofhope.org/prc

FIBROMYALGIA PAIN

The American Fibromyalgia Syndrome Association
www.afsafund.org

Fibromyalgia Network
www.fmnetnews.com

National Fibromyalgia Association
http://fmaware.org

HEADACHE PAIN

National Headache Foundation
www.headaches.org

American Council for Headache Education
www.achenet.org

TMJ Tutorial
www.rad.washington.edu/anatomy/modules/TMJ/TMJ.html

COMPLEX REGIONAL PAIN SYNDROME (CRPS) PAIN INTERNET RESOURCES

Reflex Sympathetic Dystrophy Syndrome Association of America
www.rsds.org

American RSDHope Group
www.rsdhope.org

NINDS Complex Regional Pain Syndrome Information Page
from the National Institute of Neurological Disorders and Stroke
www.ninds.nih.gov/disorders/reflex_sympathetic_dystrophy/reflex_sympathetic_dystrophy.htm

PEDIATRIC PAIN

American Academy of Pediatrics
www.aap.org

KidsHealth
www.kidsheath.org

Pediatric Pain—Science Helping Children
www.dal.ca/~pedpain/pedpain.html

10. PAIN-RELATED BOOKS

(available at amazon.com and other online bookstores)

The Body in Pain: The Making and Unmaking of the World
Elaine Scarry (Oxford University Press 1985).

Cancer Pain Relief
International Association for the Study of Pain; World Health Organization, (World Health Organization 1986).

Cancer Pain Relief and Palliative Care: Report of a WHO Expert Committee, WHO Technical Report Series 804
World Health Organization (World Health Organization 1990).

Core Curriculum for Professional Education in Pain
International Association for the Study of Pain, Task Force on Professional Education, (IASP Publications 1991).

The Culture of Pain
David B. Morris (University of California Press 1993).

Dying Well: Peace and Possibilities at the End of Life
Ira Byock (Riverhead 1998).

Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness
Jon Kabat-Zinn (Delta 1990).

Handbook of Cancer Pain Management 3rd Edition
Weissman, et al. (Wisconsin Pain Initiative 1992).

How We Die: Reflections on Life's Final Chapter
Sherwin B. Nuland (Vintage 1995).

The Illness Narratives: Suffering, Healing, and the Human Condition
A. Kleinman (Basic Books 1988).

Managing Pain Before It Manages You
Margaret A. Caudill (Guilford Press 2001).

Mastering Pain: A Twelve-Step Program for Coping With Chronic Pain
Richard A. Sternbach (Putnam 1987).

Natural Pain Relief: A Practical Handbook for Self-Help
Jan Sadler, Patrick Wall (C.W. Daniel Company 2004).

Nature of Suffering and the Goals of Medicine
Eric J. Cassell (Oxford University Press, USA 2004).

On Death and Dying
Elisabeth Kubler-Ross (Scribner 1997).

Pain and Suffering
William K. Livingston, Howard L. Fields (IASP Press 1998).

Phantoms in the Brain: Probing the Mysteries of the Human Mind
V.S. Ramachandran, Sandra Blakeslee (Harper Perennial 1999).

Principles & Practice of Pain Management
Carol A Warfield, Zahid H. Bajwa (McGraw-Hill Professional Publishing; 2nd edition 2003).

Suffering
Betty Ferrell, Editor (Jones & Bartlett Publishers 1996).

The War on Pain
Scott Fishman (Harper Paperbacks 2001).

When Bad Things Happen to Good People
Harold S. Kushner (Anchor 2004).

Wherever You Go, There You Are: Mindfulness Meditation in Everyday Life
Jon Kabat-Zinn (Hyperion 2004).

Appendix B: Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory

agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*.[1] Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.[2] The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.[3] Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of

[1] As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.
[2] SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA*, 274(20) (1995): p. 1591-1598.
[3] A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised *Model Policy* is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be an important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. In addition, this policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing

the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain and update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing

patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The

Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that

some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. *Evaluation of the Patient*—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.
2. *Treatment Plan*—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
3. *Informed Consent and Agreement for Treatment*—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should

receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including
   a. urine/serum medication levels screening when requested;
   b. number and frequency of all prescription refills; and
   c. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. *Periodic Review*—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.
5. *Consultation*—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. *Medical Records*—The physician should keep accurate and complete records to include
   a. the medical history and physical examination,
   b. diagnostic, therapeutic and laboratory results,
   c. evaluations and consultations,
   d. treatment objectives,
   e. discussion of risks and benefits,
   f. informed consent,
   g. treatments,
   h. medications (including date, type, dosage and quantity prescribed),
   i. instructions and agreements and
   j. periodic reviews.

   Records should remain current and be maintained in an accessible manner and readily available for review.
7. *Compliance With Controlled Substances Laws and Regulations*—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors